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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/959,391 10/28/97 GREENHUT

S 3532/E1

EXAMINER

QM41/0924

TIBERIU WEISZ
GOTTLIEB RACKMAN AND REISMAN
270 MADISON AVENUE
NEW YORK NY 10016

ART UNIT PAPER NUMBER

3737

DATE MAILED:

09/24/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/28/97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-48 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 10-12, 14, 23-26, 28-30, 32-35, 37, 38, AND 44 is/are rejected.

☒ Claim(s) 8, 9, 13, 15-22, 27, 31, 36, 39-43, AND 45-48 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on April 24, 1998. This document has been made of record in the file as Paper No.2.

Claim Rejections - 35 USC § 112

2. Claims 2-7, 12, 14, 25, 28-30, 32-35, 37, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claims 2 and 3, the claims are indefinite in that the claimed "minute volume" is not part of the pacemaker or its circuits. To overcome this rejection, the Examiner suggests positively reciting the pacing circuitry or "means" used to monitor this parameter rather than the parameter itself.

In regard to claims 4 and 12, the claims are indefinite in that, as written, they describe a method step of "adding" and "subtracting" values rather than positively claiming the structures of the corresponding adding and subtracting circuits.

In regard to claim 6, the claim is indefinite. As written, the claim language is merely explanatory. No additional positive structure is recited.

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In regard to claims 5, 7, 14, 35, and 37, the claims are indefinite in that, as written, the claims relate more to method steps of “adjusting” a metabolic parameter rather than to a “means for adjusting” to perform the claimed adjustments.

In regard to claims 14 and 35, the claims are indefinite in that the word “adjoining” (line 1) is confusing. This appears to be a typographical error.

In regard to claim 25, there is no antecedent basis for the term “the minute volume”. To overcome this rejection, the Examiner suggests restating this as “a minute volume”.

In regard to claim 28, the claim is indefinite because, as written, no additional positive structure is recited to further limit the “metabolic parameter”. To correct this deficiency, the Examiner suggests replacing the word “is” with “comprises”.

In regard to claims 29 and 30, the claims are indefinite in that, as written, they describe the generating functions of the “metabolic demand detector” and “controller”, respectively, rather than positively claiming the structures which make this possible.

In regard to claims 32 and 33, the claims are indefinite. As written, both claims merely recite the functions of the “adjusting means” and the “exercise detector” rather than positively claiming the circuitry or structures which permit these functions.

In regard to claim 34, the claim is incomplete and indefinite because it is unclear what the statement “comparing a memory” means. The Examiner believes this is probably a typographical error and suggests changing this to “comprising” to overcome this rejection.

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In regard to claim 44, the claim is indefinite. As written, the claim describes the structures of “peaks” and “valleys” but fails to positively recite any additional method step.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Reuter et al ‘524.

The Reuter et al ‘524 describes an implantable pacemaker 10 (Fig.2) reciting all of applicant’s claimed features including cardiac activity sensors 20,66, a “pacing generator” 68, a “respiration sensor” 82,100, and a controller 50. Applicant’s attention is particularly directed to the language in claim 2 of the patent.

In regard to claim 11, applicant’s attention is directed to box 310 (Fig.3).

5. Claims 10, 11, 23, 26, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Bardy et al ‘425.

The Bardy et al ‘425 patent also describes an implantable pacemaker having all of applicant’s claimed features (Fig.3). The Bardy et al pacemaker comprises a “cardiac activity

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sensor” **300**, a “pacing generator” **314**, a “respiration sensor” **320** (col.7, lines 36-38), and a “controller” **312**.

In regard to claim 11, the pacing intervals of the Bardy et al pacer are adjusted based upon the sensed signals generated by the “respiration sensor” (col.7, lines 29-38). Applicant’s attention is also directed to boxes **436,438** (Fig.4B).

In regard to claims 23 and 26, applicant’s attention is directed to element **82** (Fig.2).

In regard to claim 38, the applicant’s attention is directed to Fig.4B. The Bardy et al pacer paces at one stimulation level and may be adjusted either upward (box **438**), downward (box **450**), or kept the same (box **436**). Commands are generated in software to pace the ventricle **412** (Fig.4A).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 10, 23-25, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al ‘740 in view of Bardy et al ‘425.

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The Nappholz et al '740 patent describes an implantable pacemaker (Fig.1) comprising most of applicant's claimed features including a sensor **14**, a pace generator **16**, a "metabolic demand detector" **32**, and a microprocessor **20** which further includes circuits **44,46** (Fig.4) that perform the function of the "adjuster circuit". Unlike applicant's device, however, the Nappholz pacer utilizes an "activity sensor" instead of a "respiration sensor", as claimed by the applicant.

The Bardy et al '425 patent describes an implantable pacemaker, described *supra*, which teaches the use of a sensor **320** which can either be an "activity sensor" or a "respiration sensor" (col.7, lines 36-38).

To have substituted a "respiration sensor" for the "activity sensor" on the Nappholz et al '740 device would have been obvious to one of ordinary skill in view of the teachings of Bardy et al that any "types of well known [sensors]" could be used in combination with heart sensors in implantable pacers to produce a signal "indicative of a patient's physiological demand...this signal may in turn be used to correspondingly regulate the pacing rate" (col.7, lines 40-43).

Allowable Subject Matter

8. Claims 3-7, 12, 14, 28-30, 32-35, 37, and 44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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9. Claims 8, 9, 13, 15-22, 27, 31, 36, 39-43, and 45-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Tockman et al '727 patent describes the pertinent feature of a "respiratory sensor" 52 used with a pacer. Unlike applicant's device, however, this sensor is not physically part of the implantable device, rather it is externally located with a programmer.

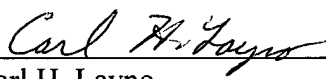
The Stein et al '632 patent describes a patent which teaches the pertinent features of monitoring inspiration and expiration of a patient's respiratory cycle (Fig.3) but which fails to describe any supporting "respiration sensor" or "metabolic" detectors.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on M-F from 8:30 AM to 5:00 PM. A voice mail message may be left if desired.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef, can be reached on (703) 308-3256. The current fax number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.



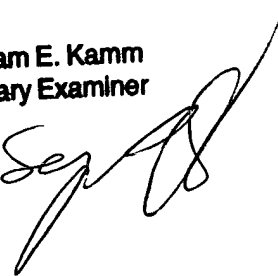
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9/18/98

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18 Sep 98